REMARKS

Claims 17-27 and 29-36 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The office Action asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular the Examiner asserts that the recitation "without remelting the composition" is new matter and requires identification of support in the specification as filed for that recitation.

Reconsideration is requested.

The issue of new matter does not arise where the added matter is inherently disclosed in the original specification. *In re Nathan*, 140 USPQ 601 (CCPA 1961), *In re Reynolds*, 170 USPQ 94 (CCPA 1971); *Kennecott Corp; v. Kyocera Int'l*, 5 USPQ2d 1194 (Fed. Cir. 1987); *Brooktree Corp. v. Advanced Micro Devices Inc.*, 24 USPQ2d 1401 (Fed. Cir. 1992)

In the preparation of a medical device article, or portion thereof, from a melt of thermoplastic polymeric material, the polymeric material will ***necessarily*** pass through a time during which it is then melted, but it will not again be remelted. (For purposes of these remarks this time is referred to as the "last melt.") By definition, the starting point of the sequence the material is melted. At the end of the process a formed article or portion thereof exists, so it is not melted at that time. To get from the melt to the formed article there is no way to avoid passing through a last melt. Because a last melt ***necessarily*** exists, it is inherently disclosed. It is not new matter to refer to it as a timing reference in the process sequence.

In the Examples the chain extender/polymer composition does not exist in a melt stage until the last melt. For instance, Example 1, page 10, lines 3-6, states:

> The components were dry mixed until CBC powders were evenly distributed in the resin. The composition was desiccant dried at 190 °F for 8-12 hours until a desired dryness was achieved ***and then extruded into tubes at a temperature in the range of 345-465 °F.***
> (emphasis added)

Prior to the extrusion an unmelted composition was formed and dried. Extrusion utilizes a melt. Therefore, the skilled person reading Example 1 will clearly understand that the melt form of the polymer composition was formed in the course of the extrusion processing. Since tubes are

produced by the extrusion (and later in the example balloons are formed from the tubes), the extrusion melt is clearly the last melt in the sequence of forming the balloon. Relative to the extrusion melt, the medical device of Example 1 is formed "without remelting the composition." The process of Example 1 therefore is performed in the sequence recited in claims 17 and 29. The remaining Examples are similar. Consequently "without remelting the composition." is not new matter.

A last melt inherently exists in the process as originally claimed. The application clearly teaches processes in which the melt form of the chain extender and polymer is prepared and reacted in the last melt. As a matter of law, no new matter has been introduced into the claims by the use of the recitation "without remelting the composition." Withdrawal of the written description rejection is therefore respectfully requested.

Finally, of the multiple alternative compounding methods described in the paragraph beginning at page 8, line 24, one method pertains specifically to compounding in a melt prior to the last melt. The specification has been amended to remove the description of that method. This has been done without prejudice to restoration in a continuing application.

Respectfully submitted,

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